REMARKS

Claims 1 and 3-41 are active in the present application.

At the outset, Applicants wish to thank the Examiner for the indication that Claims 3 and 20-23 remain allowable (see paragraph 6 on page 8 of the Office Action dated December 22, 2005). Applicants also request withdrawal of the outstanding rejections in view of the amendments above.

The rejection of Claims 1, 4-19, and 24-41 under 35 U.S.C. §112, first paragraph (written description), is obviated in part by amendment and traversed in part.

The Examiner's criticisms of the claims as lacking sufficient written description appear to center on an allegation that the specification fails to disclose a genus of variants for the compounds of Formula (1) having inhibitory activity against MSH and their use as an active ingredient in a MSH inhibitory composition, a whitening agent, an immunofunction controlling agent, an appetite controlling agent, or cosmetic preparation (see page 3, lines 5-9 of the Office Action mailed December 22, 2005). The Examiner also alleges that the specification fails to describe how to identify an active amino acid, dipeptide or tripeptide compound within the scope of Formula (1).

Applicants remind the Examiner that MPEP § 2163.02 states:

> An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

To this end, Applicants again direct the Examiner's attention to the painfully detailed description in the specification at pages 5 and 8-16 of the genus of variants for the

compounds of Formula (1). Applicants submit that the specification at pages 5 and 8-16 provides a more than adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph. Further, it is believed that substantially all of the claimed genus would be functional for the intended purpose. In fact, contrary to the Examiner's allegations, it is readily apparent to the skilled artisan on the basis of this disclosure of how to determine and identify functional members of the claimed genus.

The further basis for this ground of criticism by the Examiner is that the examples presented in the present specification are not so broad as to embrace a diverse sampling of the claimed genus. However, the Examiner is reminded that the MPEP states in §2164.02:

> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

Therefore, the failure to recite and/or exemplify each any every possible diverse member of the claimed genus and explicitly demonstrate its operability within the claimed invention is of no matter. The question that should be asked is whether the scope of the claimed invention is described in accordance with the standard of *In re Gostelli.* Applicants submit that, indeed, the specification does.

To demonstrate the same, Applicants **submit herewith** a Declaration under 37 C.F.R. §1.132 executed by Dr. Eiji Shiojiri and Dr. Yoshinobu Takino ("the Shiojiri & Takino Declaration"). In the Shiojiri & Takino Declaration, a diverse spectrum of compounds within the scope of the originally claimed invention and the currently claimed invention were prepared. Subsequently, these compounds were assayed for melanocyte-stimulating hormone (MSH) inhibitory activity consistent with the description on pages 16-19 of the specification and the Test Examples. What is apparent from the Shiojiri & Takino Declaration is that the

skilled artisan can readily produce the compounds of the claimed invention and can readily identify and appreciate the active compounds, especially those that have inhibitory activity against MSH.

Moreover, Applicants direct the Examiner's attention to page 16, line 12 to page 19, line 2, which provides a full and detailed description of how to identify an *active* amino acid, dipeptide or tripeptide compound within the scope of Formula (1). Further, pages 19-24 describe how the skilled artisan would prepare compositions containing the compounds meeting the claimed activity limitation (see Claim 4). And, still further, Applicants direct the Examiner's attention to the Shiojiri & Takino Declaration enclosed herewith that further illustrates the sufficiency of the present disclosure.

Moreover, Applicants direct the Examiner's attention to pages 25-43 in which Applicants have exemplified several synthetic methods to produce compounds of Formula (1) and methods by which the activity of the same may be ascertained. In particular, Applicants wish to now Test Examples 1, 2, and 4 by which the skilled artisan may readily identify functional compounds. Again, the Examiner is reminded of the standard for determining compliance with the written description requirement set forth in MPEP § 2163.02. In view of the foregoing, Applicants submit that in view of the extensive description in the specification the skilled artisan would be able to readily recognize that which they have invented and claimed.

In view of the foregoing, Applicants submit that the skilled artisan would readily appreciate the scope of the claims as presently presented. As such, Applicants request withdrawal of this ground of rejection.

The rejections of: (a) Claim 1 under 35 U.S.C. §102(b) and/or under 35 U.S.C. §103(a) over Iwama et al; and (b) Claim 24 under 35 U.S.C. §102(b) and/or under 35 U.S.C. §103(a) over Isler, are obviated by amendment.

Applicants have amended the claims to more specifically define the compounds or peptides of Formula (1). Specifically, Claims 1 and 24 have been amended to exclude the mono-peptides define in Iwama et al and Isler.

Claim 1 has been amended to define "m" as being "1." The compounds cited by the Examiner at column 4, lines 44-69, each require "m" to be "0." Therefore, Iwama et al does not anticipate the invention currently claimed in Claim 1.

With respect to Claim 24, Applicants have maintained the scope of the previously present claim when "m" is "1." However, when "m" is "0" Applicants have limited the scope of compounds to require that R^6 be an NHY group. In the compound disclosed by Isler (1-napththylacetyl-leucine), which the Examiner alleges to anticipate previously pending Claim 24, "m" is "0" and R6 is a hydrogen atom. Therefore, Isler clearly does not anticipate the invention currently claimed in Claim 24.

In view of the foregoing amendment, Applicants submit that neither Iwama et al nor Isler disclose or suggest a compound falling within the scope of the presently claimed invention. The standard for determining anticipation requires that the reference "must teach every element of the claim" (MPEP §2131). Therefore, the failure of Iwama et al or Isler to specifically disclose or suggest a compound or peptide within the scope of the claimed invention would necessarily make these references fail to anticipate the claimed invention.

Moreover, Applicants submit that the asserted art of record cannot even support a *prima facie* case of obviousness. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation... to modify the

reference... Second, there must be a reasonable expectation of success. Finally, the prior art reference... must teach or suggest all the claim limitations." (MPEP §2142) Applicants note that neither Iwama et al nor Isler provides any motivation or suggestion to modify their disclosures to arrive at the claimed invention.

In view of the foregoing, Applicants request withdrawal of the rejections over Iwama et al and Isler. Acknowledgment to this effect is requested.

The rejection of Claim 25 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Claim 25 has been amended to ensure that it is narrower in scope than Claim 24 from which it depends.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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